

Practitioner's Docket No. U 013108-9

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Chong Jin OON, et al.

Serial No.: 09/719,533

Group No.: 1653

Filed: July 10, 2001

Examiner: Donna C. Wortman

FOR: A VACCINE-INDUCED HEPATITIS B VIRAL STRAIN AND USES THEREOF

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

STATEMENT OF BIOLOGICAL CULTURE DEPOSIT

WARNING: *Submission of a letter related to a biological deposit after a Notice of Allowance may subject an application to a reduction in patent term adjustment under 37 C.F.R. 1.704(c)(10). See Notice of May 29, 2001, 1247 OG 111-112, June 26, 2001.*

I, CLIFFORD J. MASS
Name of Applicant or Assignee or Assignee's representative

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is **mandatory**;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

- ☒ with sufficient postage as first class mail. ☐ as "Express Mail Post Office to Address"
Mailing Label No. _____ (mandatory)

TRANSMISSION

- ☐ transmitted by facsimile to the Patent and Trademark Office to (571)-273-8300.

Signature

CLIFFORD J. MASS

(type or print name of person certifying)

Date: August 3, 2005

***WARNING:** *Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b). "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*
(Statement of Biological Culture Deposit--page 1 of 4) 9-25

hereby state:

1. That the following culture(s) referred to in the specification of this application have been deposited:

Hepatitis B Virus Surface Antigen
-‘S’- 145 Singapore Strain

P 97121504

Strain

Accession number

Hepatitis B Virus Surface Antigen
-‘S’- 145 Singapore Strain

P 97121505

Strain

Accession number

Hepatitis B Virus Surface Antigen
-‘S’- 145 Singapore Strain

P 97121506

2. That the date of the above deposit is:

(check appropriate item below)

☒ before the U.S. filing date of this application.

☐ after the U.S. filing date of this application and proof that the culture(s) identified above is(are) the same culture(s) described in the application as filed is attached.

3. That the name and address of the depository is:

European Collection of Cell Culture

Name of depository

Vaccine Research and Production Laboratory

Address of depository

Public Health Laboratory Service Centre for Applied Microbiology and Research Porton Down
Salisbury, Wiltshire SP40JG, UK

4. That a statement that the culture(s) deposited with the above named depository was (were) viable and was (were) capable of reproduction, if appropriate, on the date of deposit is attached. Such statement is executed by:

(complete a, b or c below)

a. ☒ the depository.

b. ☐ the applicant.

c. ☐ a competent third party.

WARNING: *If the applicant himself or a competent third party makes the statement that the microorganism is viable and is capable of reproduction, if appropriate, then the tests must have been performed on a sample certified to have been (1) received by the depository with the same samples actually deposited and (2) promptly returned to applicant.*

5. That, with respect to the permanence of the culture(s) deposit:

(complete a, b, or c)

- a. ☒ the depository is an official depository, in accordance with the Budapest Treaty for the above deposited culture(s).
- b. ☐ the depository affords permanence of the deposit for at least 30 years or at least 5 years after the most recent storage request, whichever is longest.
- c. ☐ evidence that permanent availability of the microorganism is assured is provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited culture(s).

I state that should the microorganism(s) mutate, become nonviable or be inadvertently destroyed, applicants will replace such microorganism(s) for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, whichever period is longer.

6. That, with respect to availability of the culture(s), I state that the deposit has been made under conditions of assurance of (a) ready accessibility thereto by the public if a patent is granted whereby all restrictions to the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent (M.P.E.P. 608.01 (p)), and (b) access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. section 1.14 and 35 U.S.C. section 122.

- ☐ Evidence of the accessibility of the culture(s) as set forth above is provided in the form of the attached copy of the contract with the above mentioned depository with respect to the deposited cultures.

August 3, 2005

Date

Ladas & Parry

P.O. Address of Signatory

26 West 61st Street

New York, NY 10023

CLIFFORD J. MASS

(type or print name of person signing)

Signature

- ☐ Inventor
☐ Assignee of complete interest
☒ Person authorized to sign on behalf of assignee

(complete the following, if applicable)

(type name of assignee)

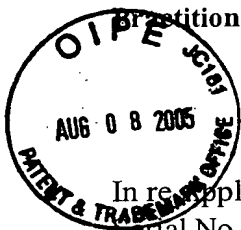
Address of assignee

Title of person authorized to sign on behalf of assignee: _____

Assignment recorded in PTO on _____

Reel _____ Frame _____

A "STATEMENT UNDER 37 C.F.R. 3.73(b)" is attached.



Applicant's Docket No. U 013108-9

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Chong Jin OON, et al.

Serial No.: 09/719,533

Group No.: 1653

Filed: July 10, 2001

Examiner: Donna C. Wortman

FOR: A VACCINE-INDUCED HEPATITIS B VIRAL STRAIN AND USES THEREOF

Mail Stop Sequence

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

**SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY,
AND/OR AMENDMENT PERTAINING THERETO
FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE
~~AND/OR AMINO ACID SEQUENCE~~**

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

*(When using Express Mail, the Express Mail label number is **mandatory**;
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

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37 C.F.R. 1.8(a)

37 C.F.R. 1.10*

- ☒ with sufficient postage as first class mail.

- ☐ as "Express Mail Post Office to Address"
Mailing Label No. _____ (mandatory).

TRANSMISSION

- ☐ transmitted by facsimile to the Patent and Trademark Office. to **(703) 872-9306**

Date: August 3, 2005

Signature

CLIFFORD J. MASS

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

(check and complete this item, if applicable)

1. ☒ This replies to the Office Letter dated May 3, 2005.

NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the serial number from the return post card or the attorney's docket number added.

- ☐ A copy of the Office Letter is enclosed.

IDENTIFICATION OF PERSON MAKING STATEMENT

2. I, CLIFFORD J. MASS
(type or print name of person signing below)

state the following:

ITEMS BEING SUBMITTED

3. Submitted herewith is/are

(check each item as applicable)

- A. ☒ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. 1.821(c) and 37 C.F.R. 1.822 and 1.823.
- B. ☒ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. 1.821(d).
- C. ☒ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. 1.821(e) and 1.824.
- D. ☐ Please transfer to this application, in accordance with 37 C.F.R. 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

In re application of:

Serial No.:

Filed:

For:

Group No.:

Examiner:

The Computer readable form(s) of applicant's other application corresponds or compares to the "Sequence Identifier(s)" of this application as follows:

Computer Readable Form
(other applications)

"Sequence Identifier"
(this application)

NOTE: "If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference may be made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified." 37 C.F.R. 1.821(e).

E. ☒ A statement that the content of each "Sequence Listing" submitted and each computer readable copy are the same, as required in 37 C.F.R. 1.821(f).

☐ Because the statement is not made by a person registered to practice before the Office, the Statement is verified as required in 37 C.F.R. 1.821(b).

F. ☒ Because this submission is made in fulfilling the requirement under 37 C.F.R. 1.821(g), a statement that the submission includes no new matter.

☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. 1.821(g).

**STATEMENT THAT "SEQUENCE LISTING"
AND COMPUTER READABLE COPY ARE THE SAME
AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER**

4. I hereby state:

(complete applicable item A and/or B)

A. ☒ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.

B. ☒ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

STATUS

5. Applicant is

☐ a small entity:☒ other than a small entity.**EXTENSION OF TERM**

6.

NOTE: 37 C.F.R. § 1.704(b)". . . an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph."

NOTE: "Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec. 10, 1985 (1061 O.G. 34-35).

NOTE: See 37 C.F.R. 1.645 for extensions of time in interference proceedings and 37 C.F.R. 1.550(c) for extensions of time in reexamination proceedings.

7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply.

(complete (a) or (b) as applicable)

(a) ☐ Applicant petitions for an extension of time under 37 C.F.R. 1.136 (fees: 37 C.F.R. 1.17(a)(1)-(4)) for the total number of months checked below:

<u>Extension (months)</u>	<u>Fee for other than small entity</u>	<u>Fee for small entity</u>
<input type="checkbox"/> one month	\$120.00	\$60.00
<input type="checkbox"/> two months	\$450.00	\$225.00
<input type="checkbox"/> three months	\$1,020.00	\$510.00
<input type="checkbox"/> four months	\$1,590.00	\$795.00

Fee \$ _____

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- [] An extension for _____ months has already been secured, and the fee paid therefor of \$ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ _____

OR

- (b) [] Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

FEE PAYMENT

8. [] Attached is a check in the sum of \$ _____.
- [] Charge Account No. _____ the sum of \$ _____.
A duplicate of this transmittal is attached.

FEE DEFICIENCY

9.

NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.

10. [X] If any additional extension and/or fee is required, charge Account No. 12-0425.

SIGNATURE(s)

(type or print name of person signing statement)

CLIFFORD J. MASS

Signature

August 3, 2005

Date

P.O. Address of Signatory

c/o Ladas & Parry LLP
26 West 61st Street
New York, N.Y. 10023

(If applicable)

Tel. No.: (212) 708-1890

Reg. No. 00140

- [] Inventor
[] Assignee of complete interest
[] Person authorized to sign on behalf of assignee
[X] Practitioner of record
[] Filed under Rule 34(a)
[] Registration No. _____
[] Other _____

(specify identity of person signing)

(complete the following, if applicable)

(type name of assignee)

Address of assignee

Title of person authorized to sign on behalf of assignee

A "STATEMENT UNDER 37 C.F.R. 3.73(b)" is attached.

Assignment recorded in PTO on _____

Reel _____ Frame _____

Reg. No.

Tel. No.: ()

SIGNATURE OF PRACTITIONER

(type or print name of practitioner)

P.O. Address

c/o Ladas & Parry LLP
26 West 61st Street
New York, N.Y. 10023

Customer No.:



00140

PATENT TRADEMARK OFFICE